IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

BEATRICE GRINAGE, as Personal Representative of Aaron Grinage, Deceased	:	
v.	:	Civil No. CCB-11-1436
MYLAN PHARMACEUTICALS, INC.	:	

MEMORANDUM

Beatrice Grinage ("Grinage" or "plaintiff") brought this action against Mylan Pharmaceuticals, Inc. and its parent company Mylan, Inc. (collectively, "Mylan" or "defendants") after her husband ingested Allopurinol, a Mylan-manufactured drug, and then developed a skin disease that led to his death. Acting as her husband's personal representative, Grinage alleges Mylan is liable for both compensatory and punitive damages under state law theories of negligence, strict products liability, fraud, and breach of implied warranty. Grinage originally brought suit in Maryland state court, and Mylan removed to this court on the grounds of diversity jurisdiction, as Grinage is a resident of Maryland, Mylan, Inc. is incorporated in Pennsylvania, and Mylan Pharmaceuticals, Inc. has its principal place of business in West Virginia. Grinage subsequently filed an amended complaint, and Mylan filed a Fed. R. Civ. P. 12(b)(6) motion to dismiss. The company argues that pursuant to *Pliva, Inc. v. Mensing*, 564 U.S. ----, 131 S. Ct. 2567 (2011), federal law and FDA regulations pre-empt the state law claims raised. The issues have been fully briefed, and no hearing is necessary. *See* Local Rule 105.6. For the reasons stated below, the defendant's motion will be granted and this suit will be dismissed.

BACKGROUND

On January 21, 2008, Aaron Grinage received a prescription for Allopurinol tablets for treatment of gout. (Am. Compl. ¶ 7, ECF No. 22.) The tablets were manufactured and marketed by the defendant, Mylan. (*Id*. at ¶ 10.) Mr. Grinage took Allopurinol for approximately one month before he was diagnosed with Stevens-Johnson Syndrome, a skin disease, and then with Toxic Epidermal Necrolysis, a related but more severe skin reaction. (*Id.* at ¶¶ 22–26.) On March 8, 2008, he suffered multi-system organ failure and died. (*Id.* at ¶ 28.)

Allopurinol is a generic version of Zyloprim, a brand-name drug the FDA approved in 1966. (*Id.* at ¶ 8.)[1] Mylan alleges, and Grinage does not dispute, that the warning label for Allopurinol "is and has always been substantially identical to the warning contained in the labeling of . . . Zyloprim." (Def.'s Mot. to Dismiss 5–6.) The labels for both products state that the "most frequent adverse reaction to [the drug] is skin rash" and that "[s]kin reactions can be severe and sometimes fatal." (Def.'s Mot. to Dismiss, Exs. B, C.) Both labels report the skin reactions of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis are "probably causally related" to ingestion of the drug. (*Id*.) The labels cite one study that found that 3% of patients had skin reactions, but they further note that "with current usage, skin reactions have been observed less frequently than 1%." (*Id*.)

In Grinage's amended complaint she alleges that Mylan "knew or should have known that the risk" of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis "was greater than 1% referenced in the label [sic]." (Am. Compl. ¶ 14.) The complaint further alleges that Mylan

[1] The original Zyloprim patent-holder, Prometheus Labs, continues to manufacture and sell the drug. (Am. Compl. ¶¶ 10–13.)

was "negligent in failing to report published articles and overwhelming scientific evidence of increased risks" to the FDA, the brand name manufacturer, healthcare providers, and patients. (*Id*. at ¶ 15.) As a result, Grinage concludes, the decedent consumed a product that "caused unreasonably dangerous risks," (*id.* at ¶ 43), and was "not safe or fit for its intended purpose." (*Id.* at ¶ 75.) In all, the complaint articulates independent claims of negligence, strict liability, fraud, and breach of implied warranty. Based on these claims, the complaint seeks compensatory and exemplary damages for wrongful death. In response, Mylan has filed a 12(b)(6) motion to dismiss.

STANDARD OF REVIEW

"[T]he purpose of Rule 12(b)(6) is to test the sufficiency of a complaint and not to resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006) (internal quotation marks and alterations omitted) (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999)). When ruling on such a motion, the court must "accept the well-pled allegations of the complaint as true," and "construe the facts and reasonable inferences derived therefrom in the light most favorable to the plaintiff." *Ibarra v. United States*, 120 F.3d 472, 474 (4th Cir. 1997). "Even though the requirements for pleading a proper complaint are substantially aimed at assuring that the defendant be given adequate notice of the nature of a claim being made against him, they also provide criteria for defining issues for trial and for early disposition of inappropriate complaints." *Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009).

To survive a motion to dismiss, the factual allegations of a complaint "must be enough to

raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations and alterations omitted). Thus, the plaintiff's obligation is to set forth sufficiently the "grounds of his entitlement to relief," offering more than "labels and conclusions." *Id.* (internal quotation marks and alterations omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not 'show[n]' - 'that the pleader is entitled to relief.'" *Ashcroft v. Iqbal*, -- U.S. --, 129 S. Ct. 1937, 1950 (2009) (quoting Fed. R. Civ. P. 8(a)(2)).

ANALYSIS

Mylan argues that Grinage's claims are pre-empted by federal law and related FDA regulations. The argument relies on the Supreme Court's recent decision in *Pliva, Inc. v. Mensing*, 564 U.S. ----, 131 S. Ct. 2567 (2011). The *Mensing* Court reviewed facts similar to those at issue here, and the Court barred the plaintiffs' state law tort claims under the pre-emption doctrine of impossibility. *Id.* at 2577. Impossibility, the Court explained, is a species of conflict preemption. *Id.* (citing *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)). "Where state and federal law directly conflict, state law must give way." *Mensing*, 131 S. Ct. at 2577. Mylan contends that the *Mensing* decision is "dispositive" of all of Grinage's claims. (Def.'s Reply 2.)

In *Mensing*, the Court consolidated two cases where plaintiffs had sued generic drug manufacturers using Louisiana and Minnesota state-law tort theories. 131 S. Ct. at 2573. Plaintiffs pleaded that the drug manufacturers "knew or should have known of the high risk" of

the neurological injuries at issue and "knew or should have known that their labels did not adequately warn of that risk." *Id.* at 2574. The Court concluded it was impossible for the manufacturer–defendants to satisfy state products liability laws without violating FDA regulations that require generic drugs to have the same labels as their brand-name counterparts. *Id.* at 2577–78. The statutory language and regulations related to the Drug Price Competition and Patent Term Restoration Act ("Hatch Waxman") and the FDA's interpretation of these rules "require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'" *Id*. at 2574–75 (citing 57 Fed. Reg. 17961 (1992)); *see also* 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(4)(G); 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7). So even if a generic manufacturer had new information about side effects, it could not change its label unless the brand-name manufacturer did so first, or unless the FDA instructed all manufacturers to do so. As a result, pursuant to impossibility pre-emption doctrine, federal law pre-empts any state law tort action that creates liability for generic manufacturers who fail to take independent action to change their labels. *Mensing*, 131 S. Ct. at 2577–81.

State products liability laws generally recognize three different types of actionable product defects: "(1) design defects, (2) manufacturing defects, and (3) labeling defects (e.g., failure to warn)." *Bruesewitz v. Wyeth LLC*, 562 U.S. ----, 131 S. Ct. 1068, 1087 (2011) (Sotomayor, J., dissenting). According to Grinage, *Mensing* stands only for the limited proposition that a failure-to-warn claim is pre-empted when a plaintiff avers that a generic drug manufacturer "was required to alter the content of FDA-approved labeling by seeking FDA action." (Pl.'s Resp. to Mot. to Dismiss 2.) Thus, Grinage argues, *Mensing* does not affect her

negligence and strict liability claims based on failure to warn, at least to the extent that the failure to warn arises from either (1) an independent "duty to effectively communicate warnings" or (2) defendants' alleged failure to convey warning inadequacies to Prometheus Labs, the brand-name manufacturer of Zyloprim. (*Id*. at 4.) Likewise, she argues, her negligence claims also survive pre-emption under a defective design theory, and her breach of implied warranty and fraud claims are similarly unaffected.[2] The court reviews each of these claims in turn.

A. Failure to Warn

The plaintiff's alternative failure-to-warn theories fail either by preemption under *Mensing* or for failure to state a claim under *Iqbal* and *Twombly*.

Grinage first argues that this court should, in determining whether a drug is defective under a failure-to-warn theory, use a two-prong test considering both (1) the "substantive adequacy" of warnings, and (2) the overall "efficacy of communication." (Pl.'s Resp. to Mot. to Dismiss 4–6.) Grinage suggests various methods Mylan could have employed for more effective communication to healthcare providers and consumers, including through Dear Doctor letters, training programs, or "prominent professional or public notifications." (*Id*. at 9.)

Of these proposed alternative methods of communication, the *Mensing* Court directly addresses only the use of Dear Doctor letters. Because these letters themselves qualify as "labeling," FDA regulations require any letter sent by a generic manufacturer to be "consistent

[2] The complaint also alleges that *Mensing* does not apply to any claims arising after the enactment of the 2007 Food and Drug Administration Amendments Act (FDAAA), 121 Stat. 823 *et seq*. (Am. Compl. ¶ 38.) In its motion to dismiss, Mylan contends that "the FDAAA did not eliminate or amend any of the statutes or regulations relied upon in *Mensing* and it therefore has no impact on the preemption analysis." (Def.'s Mot. to Dismiss 16–18.) Grinage failed to address this argument in her response, so the court will treat this claim as abandoned. *See, e.g., Ferdinand Davenport v. Children's Guild*, 742 F. Supp. 2d 772, 777 (D. Md. 2010) ("By her failure to respond to [defendant's] argument" in a motion to dismiss, "the plaintiff abandons [her] claim.").

with and not contrary to" the drug's approved labeling. 131 S. Ct. at 2576 (citing 21 C.F.R. § 201.100(d)(1)). Grinage argues that the *Mensing* Court does not necessarily require pre-emption of state law causes of action where the duty to warn can be satisfied with Dear Doctor letters, or other methods of communication that may be more effective than labeling alone. Rather, such a duty and cause of action are preempted only to the extent that the additional communications are not consistent with the drug's labeling and therefore are prohibited by federal law. *See Brasley-Thrash v. Teva Pharm. USA, Inc.*, 2011 WL 4025734 at *2–3 (S.D. Ala. Sept. 12, 2011) (finding a failure to warn claim against a generic manufacturer not necessarily pre-empted where the claim was supported by an alleged failure to use Dear Doctor letters to disseminate information *consistent* with an updated brand-name label).[3]

The problem with Grinage's argument, as applied here, is that she provides no method of more effective communication that is "consistent with" the drug's approved labeling. She supports her failure-to-warn argument by suggesting that information about a 2007 Israeli study of Allopurinol should have been communicated to medical providers through alternative channels. (Pl.'s Resp. to Mot. to Dismiss 7.) Contrary to plaintiff's contention, however, any duty to send Dear Doctor letters that includes "substantial new warning information," like the Israeli study, is pre-empted by *Mensing*. 131 S. Ct. at 2576 ("A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling.").[4] Accordingly, Mylan cannot be held to have violated a state law duty to warn for having failed to send a Dear Doctor letter about the Israeli study. Grinage suggests other

[3] An unpublished opinion is cited not for any precedential value but for the consistency of its reasoning on this issue.
[4] The Court also reasoned that "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand name and generic drugs and thus could be impermissibly 'misleading.'" *Id*. (citing 21 C.F.R. § 314.150(b)(3)).

alternative avenues of communication as well—through training for healthcare providers and professional publications, for example. But she provides the court with no explanation why these methods of communication should be evaluated any differently from Dear Doctor letters.

Grinage may also contend that the manufacturer could have met its duty by using the various suggested alternative methods of communication *without* including substantial new warning information like the Israeli study. But, to the extent that she does make this argument, she has failed to sufficiently plead causation. Maryland courts recognize a presumption with regard to causation, that plaintiffs "would have heeded a legally adequate warning had one been given." *U.S. Gypsum Co. v. Mayor and City Council of Baltimore*, 647 A.2d 405, 413 (Md. 1994). This presumption does not, however, relieve a plaintiff of the requirement that she adequately allege causation in the first place. *See Lowe v. Sporicidin Intern.*, 47 F.3d 124, 131 (4th Cir. 1995) (upholding dismissal of a failure-to-warn claim because plaintiff's "sole allegations as to causation were the very general assertions that 'as a direct and proximate result of the allegations set forth in' the summarily pleaded counts"). Here, there is no allegation that Mr. Grinage and his doctor did not see the labeling as it was approved and take into consideration the information included therein about Stevens-Johnson Syndrome. Nor has Grinage alleged any other facts sufficient to support a reasonable inference that further communications consistent with the approved label would have affected the choices made by Mr. Grinage or his doctor. *Cf. Charleston Area Med. Ctr. v. Blue Cross & Blue Shield Mut. of Ohio, Inc.*, 6 F.3d 243, 247 (4th Cir. 1993) ("Although issues of causation are to be decided by the jury, whether the evidence is sufficient to create a jury issue is solely a question of law to be determined by the court."). Thus, while there may be a viable argument for a duty to "effectively

communicate" that survives *Mensing*, Grinage has failed to articulate how actions required by such a duty would have affected the outcome in this case.

Grinage also argues that her failure-to-warn claim survives pre-emption based on defendants' alleged failure to convey warning inadequacies to the brand-name manufacturer, Prometheus Labs. This is identical to the argument, rejected in *Mensing*, that the plaintiff could meet its duty to warn by reporting new warning information to the FDA and assuming that the FDA would then approve new labeling for all manufacturers. The *Mensing* Court held that it is not sufficient to "imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579 (emphasis in original). Instead, in order to avoid impossibility pre-emption, the private party must be able to "independently" do under federal law what state law requires of it. *Id.* Here, Prometheus is the third party referenced in *Mensing*. Grinage argues that Prometheus, as the brand-name manufacturer, would have been required by FDA regulations to make a labeling change upon receiving new information from Mylan. Then Mylan could have updated its own label without violating the federal duty of sameness. But there is no guarantee that Prometheus would change its own label after receiving communications of warning inadequacies from Mylan. Thus, Mylan cannot *independently* remedy a state law violation for inadequate labeling by communicating information to Prometheus. This second alternative failure-to-warn theory is therefore squarely rejected by *Mensing*.

B. Defective Design

Plaintiff's defective design claim must be dismissed. In Maryland, a manufacturer may

be held strictly liable under a theory of defective design only if a court determines, as a threshold matter, that the product is not "unavoidably unsafe." *See Miles Lab., Inc. Cutter Lab. Div. v. Doe*, 556 A.2d 1107, 1114–15, 1121 (Md. 1989) ("Miles Lab. I"). Defendant argues that *all* prescription drugs are "unavoidably unsafe," (Def.'s Mot. to Dismiss 13), but this conclusion does not follow from relevant Maryland case law.[5] In any event, the court need not determine whether Allopurinol meets this threshold requirement. Even if it does, Grinage's claim fails because it cannot satisfy the pleading standards of *Iqbal* and *Twombly*.[6]

Maryland courts have not conclusively settled on the proper test for a defectively designed prescription drug. Another judge in this District has applied a seven-factor test that includes several traditional risk-utility factors. *See Pease v. American Cynamid Co.*, 795 F. Supp. 755, 759 (D. Md. 1992) (applying a defective design test in a vaccine product liability case). The Maryland Court of Appeals discussed its approach to defective design claims in *Halliday v. Sturm, Ruger & Co., Inc.*, 792 A.2d 1145 (Md. 2001), involving a firearm. In *Halliday*, the court held that the risk-utility test applies only when the product malfunctions in some way. *Id.* at 1153.[7] Otherwise, courts should apply a consumer expectation test. *Id.* at 1149–51, 1158. Applying a consumer expectation test, a product is "unreasonably dangerous,"

[5] The Maryland Court of Appeals has adopted Comment k of the Restatement (Second) of Torts § 402(A), which defines and limits product liability actions against "unavoidably unsafe products." *See Miles Lab., Inc. Cutter Lab. Div. v. Doe*, 556 A.2d 1107, 1114–15, 1121 (Md. 1989) ("Miles Lab. I"). While Comment k states that unavoidably unsafe products "are especially common in the field of drugs," it does not suggest that all drugs are *per se* unavoidably unsafe. *Id*. Rather, the determination of whether a product is unavoidably unsafe requires a weighing of relevant risk/utility factors. *See Doe v. Miles Lab., Inc. Cutter Lab. Div.*, 927 F.2d 187, 191 (4th Cir. 1991) ("Miles Lab. II").

[6] That plaintiff has styled her defective design claim as a negligence claim instead of a strict liability claim does not affect this analysis. In defective design claims, the plaintiff's "ultimate burden is the same whether her claim is characterized as one for 'strict liability,' negligence or breach of warranty." *Pease v. American Cynamid Co.*, 795 F. Supp. 755, 759 n.3 (D. Md. 1992). The same is true for failure-to-warn cases. *Gourdine v. Crews*, 955 A.2d 769, 782 (Md. 2008) ("[N]egligence concepts and those of strict liability have morphed together . . . in failure to warn cases.") (internal quotation marks and citations omitted).

[7] *Halliday* involved a gun which functioned, as intended, to injure a human being.

and therefore defective in design, if it is dangerous "to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id*. at 1150 (quoting Restatement (Second) of Torts § 402A cmt. i).

Whether this court applies a consumer expectations test or a risk-utility test, Grinage's defective design case fails. The consumer expectations test considers the same factors at issue in a failure-to-warn claim, and so its application is barred by *Mensing*. An ordinary consumer forms her expectations regarding the safety of drugs from her doctor or from the drug's label. Thus, if Allopurinol is dangerous beyond the expectations of the ordinary consumer, that can only be a symptom of Mylan's failure to update its label or communicate effectively with doctors. For reasons articulated above, any state law defective design claim predicated on this theory is pre-empted by FDA labeling regulations.

The pre-emption analysis may be different, however, for design defect claims where a risk-utility test is appropriate.[8] Regardless, Grinage has failed to state a claim based on a risk-utility theory. The factual allegations included in the amended complaint are limited to allegations regarding the defendants' alleged failure to warn. The plaintiff alleges nothing with regard to the utility of Allopurinol or availability of less dangerous alternatives. While she does allege injury, a plaintiff's right to recovery in a design defect case "may not rest on any presumption from the happening of an accident." *Jensen v. American Motors Corp., Inc.*, 437 A.2d 242, 245 (Md. App. 1981). Here, no factual allegations are included that raise the right to relief on a risk-utility design defect theory above the speculative level. *See Twombly*, 550 U.S. at

[8] The court expresses no opinion as to whether a properly pled defective design claim, based on a risk-utility theory, would be pre-empted by *Mensing*.

555. Thus, a claim based on the consumer expectations test is pre-empted, and a claim based on a risk-utility test has not been sufficiently pled. The design defect claim therefore must be dismissed.

C. Breach of Implied Warranty

Because Grinage can make out no viable design defect or failure-to-warn claim, her breach of implied warranty claims must also fail. The complaint includes a claim for breach of implied warranty of merchantability and a claim for breach of implied warranty of fitness for a particular purpose. (Am. Compl. ¶¶ 70–77.) But, beyond those assertions supporting her failure-to-warn and design defect claims, no further factual allegations are made in support of the warranty claims. Without more, both warranty claims fail to meet the pleading standards of *Iqbal* and *Twombly*.

A warranty of merchantability, warranting that the product sold is fit for the ordinary purpose for which such products are used, is implied in the sale of any good, unless properly waived or modified. Md. Code Ann., Com. Law § 2-314(2)(c) (2011); *see Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 421 (D. Md. 2001). To recover on a claim for breach of implied warranty of merchantability, as with a strict liability or negligence claim, a plaintiff must prove the existence of a defect at the time the product leaves the manufacturer. *Ford Motor Co. v. General Acc. Ins. Co.*, 779 A.2d 362, 369–70 (Md. 2001). Breach can be proved by showing the existence of any of the three general types of defects: manufacturing defects, design defects, or failure to warn. *Id*. at 370 n.13 (citation omitted). Here, Grinage has not alleged a manufacturing defect, and, as discussed above, any design defect or failure-to-warn claim not

pre-empted is too speculative to survive a motion to dismiss. If no claim of defect can survive a motion to dismiss, neither can a claim for breach of implied warranty of merchantability.

Conversely, a claim for breach of implied warranty of fitness for a particular purpose does not require proof of a defect. *Id*. at 376 ("[T]he warranty of fitness sharply contrasts with the warranty of merchantability, which involves an inherent defect in the goods that existed before they left the hands of the manufacturer."). A warranty of fitness claim does, however, require that the buyer have a "particular purpose" and that the seller have reason to know of that particular purpose. Md. Code Ann., Com. Law § 2-315 (2011). A particular purpose "must be peculiar to the buyer as distinguished from the ordinary or general use to which the goods would be put by the ordinary buyer." *Ford Motor*, 779 A.2d at 375 (citations omitted); *see Bond v. Nibco, Inc.*, 623 A.2d 731, 736 (Md. App. 1993) (holding that a complaint failed to state a claim because plaintiff "nowhere alleged that he bought the [products] for a 'particular purpose' that in any way differed from the 'ordinary purpose' for which these [products] might be used"). Grinage does not aver that her husband had any particular purpose that differed from that of other consumers of Allopurinol. Moreover, there is no indication that Mylan had any knowledge of a particular purpose, if indeed her husband had one. As a result, this claim too must be dismissed.

D. Fraud

Finally, Grinage's fraud claim also fails. The basis of Grinage's fraud claim is alleged fraudulent representations made to the deceased, his prescribing physician, and to the FDA. (Pl.'s Resp. to Mot. to Dismiss 20.) None of these allegedly fraudulent representations, however,

can be the basis of a viable claim. Mylan made representations to the deceased and his prescribing physician through the drug's label. Any claim based on the errors in the label – or omissions in labeling or communications with health providers – is pre-empted by the FDA regulations for the same reason that failure-to-warn claims are pre-empted. *See Fisher v. Pelstring*, --- F. Supp. 2d ---, 2011 WL 4552464 at *20 (D.S.C. Sept. 30, 2011) (finding fraud claims pre-empted by *Mensing* because "the plaintiffs [had] not identified any mechanism by which [the manufacturer] could have independently changed or omitted the allegedly false representations on its label without first seeking the federal government's special permission and assistance.").

This leaves the allegations of fraudulent representations to the FDA to sustain a claim of fraud. But, like her design defect claim, these allegations are too thinly-pled to survive a motion to dismiss. Fraud claims are subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b). *Haley v. Corcoran*, 659 F. Supp. 2d 714, 724 n.10 (D. Md. 2009). Rule 9(b) requires a plaintiff to plead "with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). These "circumstances" include "the time, place, and contents of . . . false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999) (quoting 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1297 (2d ed. 1990)). Grinage has not satisfied these heightened pleading standards. The complaint contains no reference to any specific communication to the FDA that constituted a misrepresentation, or to any specific studies or other information improperly omitted from filings or other communications with the FDA. Fraud allegations that fail to comply with Rule 9(b)

warrant dismissal under Rule 12(b)(6). Thus, Grinage's fraud claims must be dismissed.[9]

E. Wrongful Death

Because Grinage has failed to state a claim for negligence, strict liability, breach of warranty or fraud, she has also failed to state a claim for wrongful death. In Maryland, a wrongful death action "may be maintained against a person whose wrongful act causes the death of another." Md. Code Ann., Cts. & Jud. Proc. § 3–902(a). Thus, a party can only bring a wrongful death action if a "wrongful act" occurred. *Georgia-Pacific Corp. v. Benjamin*, 904 A.2d 511, 523 n.6 (Md. 2006). A wrongful act is "an act, neglect, or default including a felonious act which would have entitled the party injured to maintain an action and recover damages if death had not ensued." Md. Code Ann., Cts. & Jud. Proc. § 3–901(e). Because Grinage cannot maintain an action or recover damages for any of the independent product liability, warranty or fraud claims she has articulated, she cannot maintain her claim for wrongful death. *See Respess v. Travelers Cas. & Sur. Co. of America*, 770 F. Supp. 2d 751, 767–68 (D. Md. 2011) (granting a 12(b)(6) motion to dismiss a wrongful death claim where complaint failed to state a claim for underlying wrongful conduct of gross negligence or intentional infliction of emotional distress).

[9] Furthermore, the Supreme Court has held that, at least as to medical devices, any claims of injury due to fraud against the FDA are pre-empted by the federal statutory scheme that "amply empowers the FDA to punish and deter fraud against the Administration, and . . . is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 348 (2001); *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 n.3 (4th Cir. 2001) (rejecting a "fraud-on-the-FDA" claim where plaintiff had argued that "but for" the fraud on the FDA, he never would have been injured). At least one federal circuit court of appeals has held that the logic of *Buckman* applies to prescription drugs as well. *See Garcia v. Wyeth-Ayerst Lab.*, 385 F.3d 961, 965–66 (6th Cir. 2004) (preempting a Michigan law that created an exception to tort immunity for claims of fraud on the FDA). There are, however, other interpretations of *Buckman*. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 95 (2d Cir. 2006) (limiting preemption to causes of action where liability is based *solely* on the basis of fraud against the FDA). Determining the exact parameters of *Buckman* is not necessary here, however, because Grinage's claims fail to meet the 9(b) pleading standards. *Cf. Henderson v. Sun Pharm. Indus.*, --- F. Supp. 2d ---, 2011 WL 4015658 at *5 n.5 (N.D. Ga. Aug. 22, 2011) (declining, in a post-*Mensing* case, to decide whether to extend *Buckman*).

CONCLUSION

In sum, the plaintiff's complaint is insufficient under the pleading standards of *Iqbal*, *Twombly*, and Rule 9(b), to state any claim that is not otherwise pre-empted. While the Supreme Court has not explicitly foreclosed all state law product liability claims against generic drug manufacturers, Grinage has failed to plead factual allegations that raise a plausible right to relief under her alternative theories.

This court acknowledges that, at least as to the plaintiff's failure-to-warn claims, the disposition of this motion to dismiss might have turned out differently had Mr. Grinage's prescription been filled with the brand-name Zyloprim instead of the generic Allopurinol. As Justice Sotomayor noted in her dissent in *Mensing*,

> [A] drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth* [*v. Levine*, 555 U.S. 555 (2009)]. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue.

131 S. Ct. at 2592. Precedent constrains this court. Unless and until the FDA modifies its regulations, or Congress further amends the governing statute, there is no authority to allow similar failure-to-warn claims to proceed against generic drug manufacturers like Mylan.

A separate order follows.

December 30, 2011
Date

/s/
Catherine C. Blake
United States District Judge